

Outcome of Direct Pulp Capping Using Calcium Hydroxide: A Long-term Retrospective Study



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ABSTRACT

Introduction: This retrospective study evaluated the long-term outcome of direct pulp capping in mature teeth using specific case selection and treatment procedures. **Methods:** Teeth with pulp exposure due to advanced caries and clinical diagnosis of reversible pulpitis were treated by direct pulp capping. Treatments were conducted over a period of 15 years by a single operator. Under magnification, caries was completely removed, the exposed pulp examined, and capped with either pure calcium hydroxide or a calcium hydroxide-based cement. The cavity was restored and the long-term outcome evaluated from 1 to >35 years. Teeth that were asymptomatic, responded to sensibility pulp tests within normal limits, and showed no radiographic periapical changes were categorized as success. Teeth with no response to pulp tests and/or showing radiographic evidence of apical periodontitis were classified as failures. The effects of independent variables (sex, age, symptoms, number and size of pulp exposures, bleeding time, capping material, bases used over the capping material, and final coronal restoration) on the outcome were evaluated. **Results:** In general, 225 teeth from 148 patients were available for follow-up examination in at least one of the evaluated periods. The success rate of the direct pulp capping procedure was 100%, 95%, 95%, 86%, and 89% at 1-, 5-, 10-, 20-, and 35-year follow-up examination, respectively. The main variable significantly affecting the treatment outcome in all follow-up periods was the quality/presence of coronal restoration ($P < .001$). Other isolated variables associated with the outcome included the size and number of pulp exposures at the 20-year follow-up, and the exposure size, capping material, and restoration type at the 35-year follow-up. Multiple regression analysis confirmed the results for exposure size ($P < .05$), and disclosed a higher proportion of failures at 5 years when varnish was used as the base. **Conclusions:** A very high success rate of the direct pulp capping with calcium hydroxide was observed, especially in the first 10 years following treatment. The main variable influencing the outcome was the quality of the coronal restoration. (*J Endod* 2023;49:45–54.)

KEY WORDS

Caries; direct pulp capping; outcome; vital pulp therapy

Advanced caries lesions are the main cause of pulp pathology¹. The management of mature teeth with deep caries lesions that exposed the vital pulp comprises either an attempt to pulp preservation through pulp capping or pulpotomy, or pulp removal to prevent further necrosis, infection, and apical periodontitis². Until a recent past, most clinicians favored the nonsurgical root canal treatment to manage these cases because of a reported high success rate for vital teeth^{3,4}, especially when compared with some follow-up studies reporting on the unpredictability of vital pulp therapy (VPT) procedures^{5,6}. A retrospective study⁵ observed a low success rate for pulp capping: 37% at 5-year follow-up decreasing to 13% at 10 years. Another study⁶ reported that direct pulp capping and partial pulpotomy were successful in only 32% and 35%, respectively, after 1 year. The unpredictable outcomes reported by previous studies for VPT had led to the concept that it should be recommended only for immature teeth and those with accidental traumatic pulp exposures^{5,7}. This has been gradually changing lately, as clinical studies and systematic reviews published in the last decade reported improved outcomes for VPT performed with bioceramic materials^{8–10}.

SIGNIFICANCE

Strict case selection and careful clinical procedures, including complete or “nonselective” caries excavation, are expected to make direct pulp capping with calcium hydroxide a predictable therapy to save caries-exposed dental pulps.

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Indirect pulp capping has been recommended as an alternative to direct pulp capping in teeth with advanced deep caries lesions, allegedly to avoid pulp exposure. This approach is mostly based on the principle that caries can be arrested if the ecology of the involved bacterial biofilm is altered and the residual bacteria are entombed, with access denied to nutrients from the diet, as a result of a proper coronal seal provided by the temporary/permanent restoration¹¹. However, because residual bacteria may remain alive and derive nutrients from the dentinal fluid, other dentin constituents, and pulp, injury to the latter is expected to be maintained^{2,12}. Total excavation and treatment of the exposed pulps have exhibited a high success rate in teeth diagnosed with reversible pulpitis^{13–15} and even in irreversible pulpitis cases^{9,16–21}.

The indication and rationale for VPT is still a matter of intense debate in the literature and different positions from endodontic associations^{22,23}. Much of the controversy is related to several drawbacks in the studies, including lack of consideration of the pathological status of the remaining pulp tissue, clinical diagnosis, number and experience of treatment providers, and case selection for each treatment modality^{18–20,24–27}. This has led to inconsistencies in systematic reviews on the VPT outcome and the factors that may influence it^{16,28}. Several variables have been suspected to influence the indication and outcome of pulp capping procedures, including patient's age, tooth type, bleeding time, number and size of pulp exposure, and capping material^{13,15,16,29}. However, much of this evidence is anecdotal and has not been consistently evaluated.

The present retrospective study evaluated the long-term outcome of direct pulp capping in mature teeth, using specific case selection and treatment procedures. The influence of several factors on the treatment outcome was also evaluated.

MATERIALS AND METHODS

Cases receiving direct pulp capping treatment for carious pulp exposure over a period of 15 years (1986–2000) were followed up for extended periods of time up to 35 years. All treatments were carried out consecutively in a private practice by a single operator (D.R.). All cases included teeth with fully formed roots and deep caries, exhibiting pulp exposure after nonselective caries excavation. Only cases for which clinical and radiographic examination resulted in the diagnosis of reversible pulpitis were subjected to direct pulp capping

procedures. The criteria for the diagnosis of reversible pulpitis were the following: (1) no history of severe spontaneous pain that prompted the patient to seek professional aid or take analgesic medication; (2) short episodes of mild or moderate discomfort arising spontaneously and lasting a short time (minutes); (3) mild or moderate sensitivity to cold or sweet stimuli; (4) pulp sensibility tests (thermal tests) with responses within normal limits or slightly exaggerated; (5) pain elicited with the application of the stimulus ceased within a few seconds or immediately upon removal of the stimulus; (6) negative results to percussion and palpation; and (7) radiographs showing normal periradicular conditions. Cases presenting with severe spontaneous pain, with a lingering painful response to pulp tests, tenderness to percussion, and radiographic periapical changes were diagnosed as with “irreversible pulpitis” and excluded.

Clinical Procedures

For each case periapical and bite-wing radiographs were exposed with the parallel technique, using a film holder (Rinn Corporation, Elgin, IL). Clinical photographs were also taken for the majority of cases (Figs. 1–2). Patients were informed that, given the depth of the caries lesions, a pulp exposure might occur during excavation and gave consent to a pulp capping procedure if indication emerged intraoperatively.

All operative procedures were performed using a magnifying device (EyeMag Pro 4x, Carl Zeiss Meditec Dentistry, Oberkochen, Germany). Periapical or mandibular block anesthesia was administered with 4% articaine with 1/100,000 epinephrine (Septanest, Septodont, Saint Maur des Fossés, France). After prophylaxis with rubber cups and a prophylactic paste and rubber dam isolation, the operative field was disinfected with a 1% sodium hypochlorite (NaOCl) solution. Unsupported enamel was drilled with high-speed diamond burs under water spray. The superficial carious dentin was then removed with low-speed burs (5000 rpm) under water spray. The deepest soft demineralized dentin was detached with sharp hand excavators without the use of caries detectors. In none of these cases was the so-called selective or partial caries removal performed (indirect pulp capping), either in a one-step or stepwise manner.

At the end of caries excavation and cavity preparation procedures, the field was flushed with air/water spray to remove all debris and the tooth, clamp, and rubber dam were once again disinfected with 1% NaOCl.

The same solution was used to disinfect the cavity and the exposed pulp, and to favor hemostasis as well. In case of prolonged bleeding, pressure was exerted with a sterile cotton pellet soaked with 1% NaOCl. Cases where bleeding could not be controlled within a 10-minute period were excluded from the capping procedure and scheduled for pulpectomy. All contaminated instruments were replaced by a new set of sterile instruments to be used in the pulp capping procedure.

As a general rule, in small exposures, the pulp wound was directly covered with Dycal (Dentsply De Trey GmbH, Konstanz, Germany), extended to the surrounding dentin. In medium/large exposures with moisture, a small amount of calcium hydroxide powder (Endodrox, Ogna, Milan, Italy) was deposited on the pulp wound with a Messing gun and adapted through gentle pressure with a sterile cotton pellet. The rationale is that Dycal, being a hydrophobic material, could not be adapted to a wet surface. On the contrary, the calcium hydroxide powder absorbs the water and can be easily adapted to a moist wound. The powder was then covered with Dycal, which was extended to the dentin surrounding the pulp exposure area.

After pulp capping, teeth with small pulp exposures were permanently restored at the same visit. In cases with large pulp exposures, the cavities were temporarily restored with a reinforced zinc oxide/eugenol cement (Intermediate Restorative Material - IRM, Caulk Dentsply, Milford, DE), and the patients invited to attend the office after a 3– to 6-month observation time. At this appointment, pulp vitality was indirectly assessed by a sensibility test by applying a cotton pellet sprayed with a refrigerating solution (PulpoFluorane, Septodont, Saint-Maur-des-Fossés, France) onto the cervical area of the tooth, and a periapical radiograph was taken. After anesthesia and rubber dam isolation, IRM was removed, together with the capping material, and the cavity was washed with 1% NaOCl. The site of previous exposure was then inspected under magnification for hard tissue barrier formation and photographs were taken. The newly formed hard tissue was covered with Dycal, and the cavity restored permanently. Teeth were restored with amalgam, composite, or, in some posterior teeth requiring cusp protection, with an indirect restoration (full crown or onlay). A final radiograph was taken after restoration.

For each case, the following clinical aspects were meticulously recorded: (1) presence of untreated caries lesion or recurrent caries in a previously restored tooth

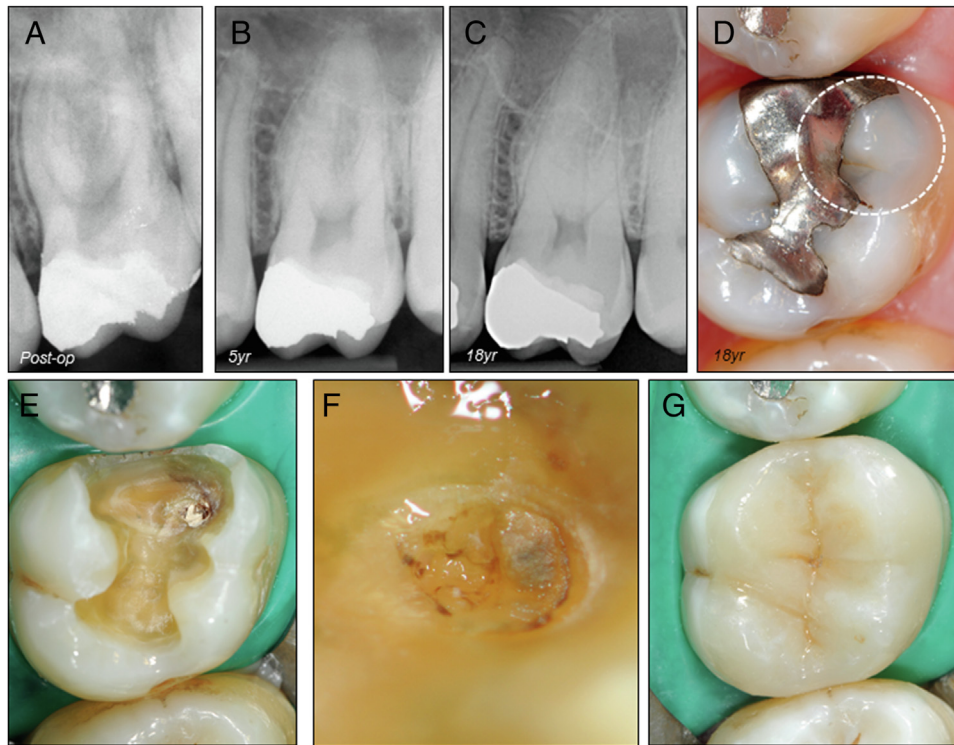


FIGURE 1 – Maxillary first molar with deep caries in a 9 year-old boy. Provoked symptoms were present. Medium exposure of the mesiobuccal pulp horn. Bleeding was controlled in <3 minutes. The exposed pulp was capped with Dycal, followed by a layer of oxyphosphate cement. Cavity restored with amalgam. (A) Postoperative radiograph. (B) Five-year follow-up radiograph. The pulp responded to tests within normal limits. (C) Radiograph taken after 18 years. The tooth was comfortable, with normal response to tests. (D) At inspection, discoloration of the mesiobuccal cusp was noted (encircled), and probing revealed recurrent caries. (E) Removal of restorative materials and carious tissue. Remnants of Dycal over the calcified barrier formed at the area of the previous pulp exposure. (F) Close-up view of the calcified bridge after removal of Dycal. (G) The crown was restored with an onlay.

preoperatively; (2) patient's report of moderate discomfort and/or provoked pain (by thermal changes, chemical stimuli, or chewing); (3) one or multiple sites of pulp exposure; size of the exposure/s (small: < 1 mm²; medium: = 1 mm²; large: > 1 mm²); (4) occurrence of bleeding at pulp exposure and its duration (<3 minutes; ≥ 3 minutes); (5) pulp capping material applied (chemically pure calcium hydroxide powder or Dycal); (5) the type of base, if any, applied over the capping material; and (6) the material used for the final permanent restoration.

Follow-up

Patients were periodically recalled at designated time intervals by phone. At each follow-up, a periapical radiograph was taken, often supplemented with a bite-wing radiograph, and pulp vitality was indirectly determined with thermal and electric pulp tests. The treatment was regarded as successful when the following factors were observed: (1) the patient reported that the tooth was comfortable and functional and not hypersensitive to temperature changes; (2) no sinus tract or gingival swelling was observed at

clinical inspection; the tooth was not mobile or tender to vertical and lateral percussion; (3) it responded to cold and electric tests within normal limits; and (4) the radiographic examination showed absence of periradicular changes, root resorption, and irregular calcification in the canals (Fig. 1B and C). In the presence of no response to pulp tests, the case was assessed as failure even though the other parameters were within normal limits.

Based on radiographs and clinical inspection, the quality of the restoration was assessed as (1) adequate, (2) inadequate, or (3) new caries present at any point along the margins of the restoration or in another area of the tooth surface. The quality of the restoration was regarded as adequate when no gaps could be observed radiographically (Figs. 3–4), and optimal adaptation was confirmed at probing under magnification, with no discoloration. On the other hand, the restoration was regarded as inadequate when, there was radiographic or visual evidence of marginal leakage (Figs. 1D, 2B and C). Under these circumstances, in the presence of normal response to pulp tests, restorative materials and caries were removed, and a new restoration was performed (Fig. 1E–G).

Statistical Analysis

Patients were evaluated at least once, starting from one year. For analysis of the pulp capping outcome, data were grouped as 1-, 5-, 10-, 20-, and 35-year follow-up. Only the patients who showed up at each specific period were included. Thus, a case that was classified as failure was no longer evaluated in the next follow-up time. Except for the age variable, to which the Student's *t* test was applied, all the other variables included in this study were of the categorical type, so the descriptive analyses and inferences were carried out comparing their distributions in relation to treatment outcome for each of the determined follow-up periods, using the chi-square or the Fisher's exact test (2 × 2 tables) and the likelihood ratio test (3 × 2 tables), as well as the odds ratio (OR) calculation.

The effects of the independent variables (sex, age, type of symptoms, number and size of pulp exposures, bleeding time, pulp capping material, other bases if any used over the capping material, and presence/quality of the final restoration) on the results in the different time periods were evaluated through multiple logistic regressions. Initially, possible

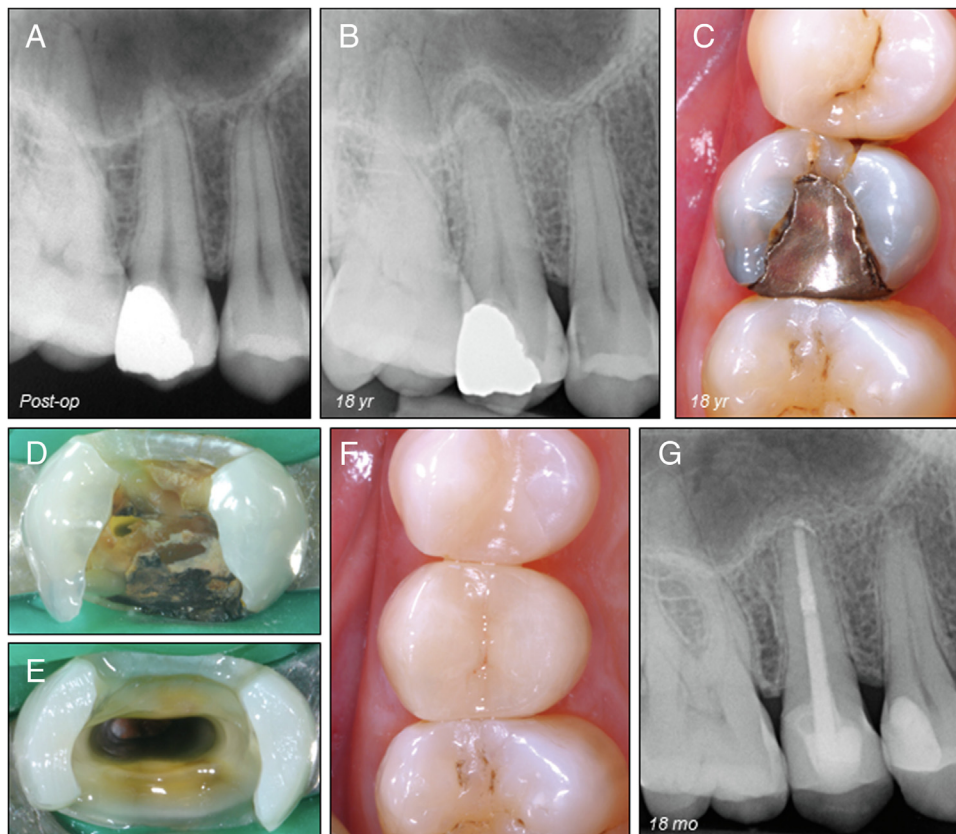


FIGURE 2 – Deep caries lesion in the maxillary premolar of a 19-year-old woman. Severe sensitivity to cold. Medium size distal exposure. Bleeding time <3 minutes. Capping with Dycal. Zinc phosphate cement was used as an intermediate base. Cavity restored with amalgam. (A) Postoperative radiograph. (B) At the 18-year follow-up the patient reported episodes of spontaneous pain and a periapical radiolucency was revealed. The tooth did not respond to thermal and electric tests. (C) Inspection showed that the restoration was no longer adequate, with evident signs of leakage. Cracks were present on the mesial ridge. (D–E) Root canal treatment was performed. (F) A glass fiber post was cemented, followed by composite build-up. A metal-free lithium-disilicate crown was cemented. (G) A follow-up radiograph taken 18 months later showed complete resolution of the apical radiolucency and the tooth was asymptomatic.

associations were independently analyzed to identify significant variables, followed by a supplementary evaluation to calculate the OR of each independent variable in relation to the dependent variable (outcome per period of time). All analyses were carried out using the Statistical Package for Social Science software version 22 (IBM, Armonk, NY), and statistical inferences were performed at a significance level of 5% ($P < .05$).

RESULTS

Of the teeth diagnosed with deep caries and reversible pulpitis, 8 were excluded due to an intraoperative diagnosis of pulp necrosis and 5 due to intraoperative impossibility to control bleeding. In general, 269 teeth were subjected to direct pulp capping procedures for carious pulp exposure over the period of the study. Of these, 2 teeth were extracted for periodontal disease and other 2 because of fracture; 9 patients (with 9 treated teeth) deceased; and

28 patients (with 31 treated teeth) moved and could not be reached. Therefore, 225 teeth from 148 patients were available for follow-up examination in at least one of the evaluated periods.

The distribution of teeth according to sex included 138 from 91 women and 87 from 57 men, with a mean age of 22.7 ± 10.3 and 22.8 ± 10.4 years, respectively. Sex and age were not significantly associated with the outcome in any of the periods evaluated ($P > .05$). The most affected teeth were mandibular and maxillary molars, and maxillary premolars (Table 1).

Table 2 shows the effects of independent variables on the pulp capping outcome. The initial analysis of isolated variables revealed that the main factor associated with the treatment outcome in all follow-up periods was the quality and presence of coronal restoration ($P < .001$). Table 3 shows the outcome in teeth with adequate and inadequate restoration, or new

caries per year. Other isolated variables associated with the outcome included the size and number of pulp exposure sites at the 20-year follow-up, and the exposure size, capping material, and type of the permanent restoration at the 35-year follow-up. Of these factors, only the exposure size was confirmed by the multiple regression analysis.

The success rate of the direct pulp capping procedure was 100%, 95%, 95%, 86%, and 89% at the follow-up examination after 1, 5, 10, 20, and 35 years, respectively (Table 3). Distribution of the failure cases was very significant, with a substantial increase after 20 and 35 years ($P < .001$). In relation to the outcome at one year, it was not possible to apply the logistic regression analysis since all the results in this period were successful. The quality/presence of coronal restoration was not included in the multiple logistic regression because the results were highly significant.

Table 4 shows the significant results of the multiple logistic regression analyses. At

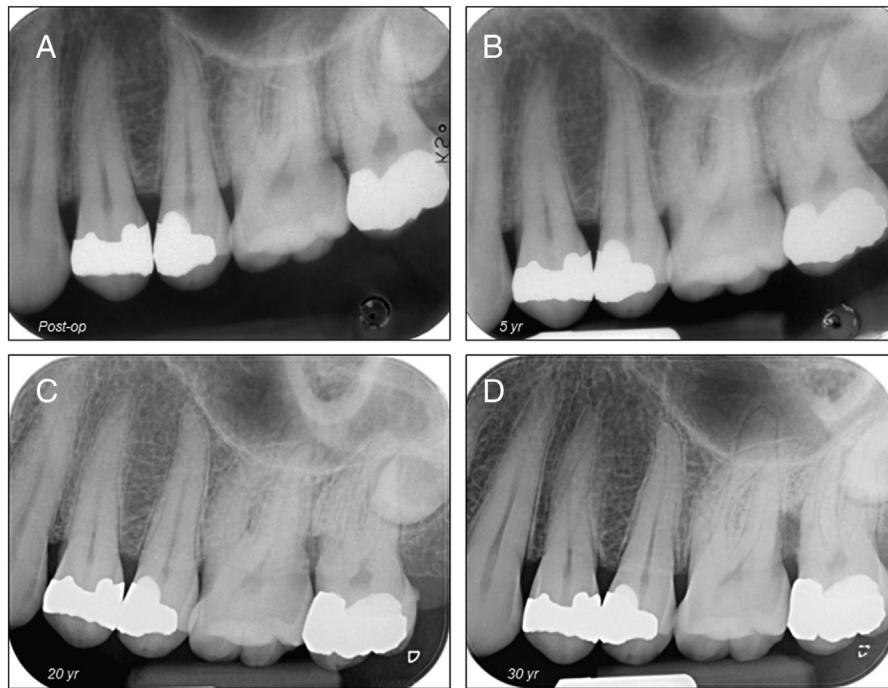


FIGURE 3 – 32-year-old woman with deep caries in the upper left quadrant. Small pulp exposures of the mesiobuccal pulp horns occurred for teeth #13 and #15. Bleeding time < 3 minutes. Capping with Dycal. Zinc phosphate cement was used as an intermediate base and cavities were restored with amalgam. (A) Postoperative radiograph. (B–D) Follow-up radiographs taken respectively after 5, 20, and 30 years. Cases were assessed as success. Pulp responded normally to sensibility tests. Normal periapical conditions. Absence of pathologic calcifications. Reduction of the pulp volume of teeth # 13 and # 15 is not dissimilar to that of neighboring teeth. Note the periodontal bone loss between teeth #14 and #15 in the long term.

5 years, the proportion of failures in teeth with large exposures was 2.51 times higher than among individuals with small ones and 1.97 times higher than those with medium ones. Also at 5 years, a significantly higher proportion of failures occurred when varnish was used as the base; OR calculations showed that the proportion of failures in the varnish group was 2.86 times higher than in the glass ionomer group and 4.06 times higher than in the zinc oxyphosphate group. Logistic regression analysis performed on data from the 10-year follow-up did not show any significant association with the set of independent variables studied. At the 20-year evaluation, teeth with medium pulp exposures showed a proportion of failures higher than the groups with small and large ones; OR calculations showed that the proportion of failures in the medium exposure group was 3.30 times higher than in the small exposure category and 3.29 times higher than in the large exposure category. Finally, the logistic regression performed on data from the 35-year follow-up showed that, similarly to the results for 20 years, teeth with medium pulp exposures had the highest proportion of failures compared with small (OR = 6.53) and large exposures (OR = 5.83).

DISCUSSION

This clinical study evaluated the long-term outcome of direct pulp capping procedures in mature vital teeth with deep dentinal caries. A large fraction of the 225 teeth available for follow-ups could be evaluated during the first 20 years (52.9% at the 1-year, 94.2% at the 5-year, 84.9% at the 10-year, 89.8% at the 20-year interval respectively), while the percentage of teeth available for the 35-year follow-up decreased to 36.4%. Factors that may influence the treatment outcome were also assessed. Pulp capping procedures were performed under controlled conditions, and findings revealed very high success rates of 100%, 95%, 95%, 86%, and 89% at 1-, 5-, 10-, 20-, and 35-year follow-ups, respectively.

Overall, the success rates observed in this study are higher than demonstrated by the majority of previous studies. In a meta-analysis of several outcome studies⁴, the weighted pooled success rate for direct pulp capping was 70.1%. The most likely reasons for the improved outcomes observed in the present study may be related to proper case selection, using teeth diagnosed with reversible pulpitis, use of magnification (for direct observation of dentin and the exposed pulp tissue), and

complete removal of all softened and infected dentin, always under stringent asepsis; these procedures have been considered as of great relevance in a protocol to treat vital teeth with deep caries and pulp exposure². It has to be stressed that the cases that are the object of the present study were performed in the period 1986–2000, using exclusively 4 × loupes and no dental microscopes, which were not common in dental practices until the end of the last century. It is highly likely that the use of an operating microscope can further improve the evaluation of the pulp wound and the surrounding dentin for case selection.

It is important to point out that the criteria for selection of cases submitted to direct pulp capping in the present study were less stringent than those developed and recommended in a recent article, where guidelines concerning the clinical procedures to be adopted for VPT were proposed². These guidelines were the result of a refinement process over the years based on histological, histobacteriological, and clinical observations, and rely mostly on direct observation of dentin and the exposed pulp tissue under deep caries. The visual characteristics of the exposed pulp are considered of utmost importance to allow a direct capping

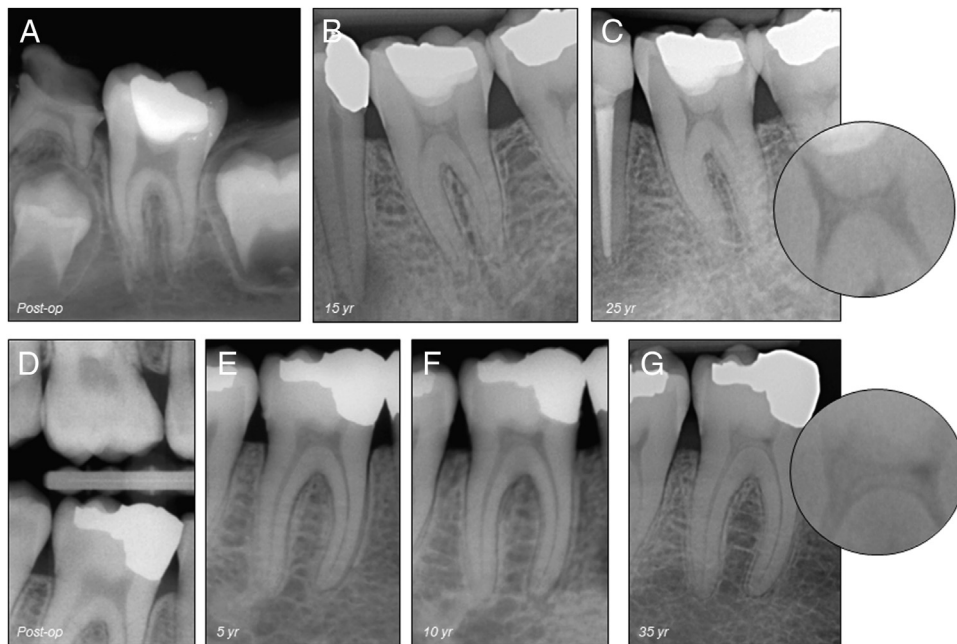


FIGURE 4 – (A) Tooth #19 with deep occlusal caries in a 9-year-old girl. Medium exposure of the mesiolingual pulp horns. Bleeding time < 3 minutes. Capping with calcium hydroxide powder. Dycal and zinc phosphate cement were applied and the cavity restored with amalgam. Postoperative radiograph. (B–C). Follow-up radiographs taken respectively after 15 and 25 years. The case was assessed as success. The pulp responded normally to sensibility tests. Normal periapical conditions. Reduction of the pulp space. Barely distinguishable calcifications in the pulp space (magnified circle). Note that pulp stones are present in the chamber of the neighboring tooth #18. (D) Tooth #30 with deep mesio-occlusal caries in a 12-year-old girl. Medium exposure of mesiobuccal pulp horns. Bleeding time <3 minutes. Capping with calcium hydroxide powder. Dycal and zinc phosphate cement applied and cavity restored with amalgam. Postoperative bite-wing radiograph. (E–G) Follow-up radiographs taken respectively after 5, 10, and 35 years. The case was assessed as success. The pulp responded normally to sensibility tests. Normal periapical conditions. General reduction of the pulp space. Progressive formation of calcified masses occupying large part of the pulp chamber volume in the last follow-up radiograph (magnified circle).

procedure: (1) red, (2) homogeneous, and (3) blood-filled tissue must be observed on the surface of the pulp wound, with no yellowish liquefied areas or dark non-bleeding zones. In the present study, only pulps with evident avascular non-bleeding tissue were excluded, while bleeding pulps were included, irrespective of their appearance.

A very high success rate was observed with calcium hydroxide as the capping material up to 20 years of evaluation. At the 1-year and 5-year follow-up, all treatments using this substance were classified as successful. At

35-year follow-up, however, the success rate decreased to two-thirds of the cases, which was statistically inferior to the results of Dycal in the initial independent variable analysis. However, this difference was not confirmed after the multiple logistic regression analysis. It is salient to point out that calcium hydroxide was used in teeth with medium to large pulp exposures, as opposed to Dycal, which was the capping material used in teeth with small exposures.

Several teeth with large pulp exposures were restored temporarily and re-accessed

after 3–6 months. The rationale was the possibility to check a favourable response of the pulp tissue before proceeding to the final crown restoration.

Several studies have compared the outcome of VPT using calcium hydroxide and mineral trioxide aggregate (MTA). When used in direct pulp capping, MTA led to significantly better results than calcium hydroxide^{9,16,29}. Curiously, studies evaluating the outcome of full and partial pulpotomy revealed no significant difference between MTA and calcium hydroxide^{30–32}. The reasons for these differences are not evident, and it is very difficult to compare data from different studies using different treatment procedures. A comparison of different materials used in different VPT procedures in the same study should be encouraged.

The high long-term success rates observed for calcium hydroxide treatment question the concept that direct pulp capping with this substance promotes unpredictable results. This misunderstanding originates from the comparison of old follow-up studies where calcium hydroxide was used (with several serious methodological issues) with more recent studies where MTA was used. These more recent studies^{8,14} were performed by

TABLE 1 - Distribution of the Different Tooth Types Included in this Study

Tooth	Sex		Total
	Female	Male	
Mandibular molar	35	26	60
Maxillary molar	25	32	57
Maxillary premolar	40	14	54
Mandibular premolar	19	6	25
Maxillary central incisor	10	6	16
Maxillary lateral incisor	5	3	8
Maxillary canine	2	0	2
Mandibular central incisor	1	0	1
Mandibular canine	1	0	1
Total	138	87	225

TABLE 2 - Distribution of Categorical Variables in Relation to the Outcome of Pulp Capping

Variable	Class	1 y			5 y			10 y			20 y			35 y		
		Success	Failure	P value	Success	Failure	P value	Success	Failure	P value	Success	Failure	P value	Success	Failure	P value
Provoked symptoms	Yes	30	0	—	50	0	.072	41	4	.208	39	8	.552	16	1	.451
	No	89	0	—	152	10		140	6		134	21		57	8	
Moderate discomfort	Yes	12	0	—	20	0	.296	17	1	.949	15	5	.153	4	1	.505
	No	107	0	—	182	10		164	9		158	24		69	8	
Bleeding time	>3 min	0	0	—	2	0	.752	1	0	.814	1	1	.149	0	0	—
	<3 min	119	0	—	200	10		180	10		172	28		73	9	
Exposure number	Simple	17	0	—	33	1	.594	31	2	.815	33	1	.037	14	3	.323
	Multiple	102	0	—	169	9		150	8		140	28		59	6	
Exposure size	Small	57	0	—	107	4	.528	96	3	.189	97	10	.015	47	3	.027
	Medium	40	0	—	63	3		55	3		47	16		12	5	
	Large	22	0	—	32	3		30	4		29	3		14	1	
Capping material	Ca(OH) ₂	17	0	—	32	0	.172	27	2	.663	28	3	.419	10	5	.002
	Dycal	102	0	—	170	10		154	8		145	26		63	4	
Other bases	Glass ionomer	16	0	—	20	1	.354	19	1	.423	16	5	.493	1	1	.074
	Varnish	5	0	—	14	7		13	0		12	2		4	1	
	Zinc oxiphosphate	85	0	—	142	5		128	9		123	19		57	6	
Permanent restoration	Amalgam	81	0	—	149	8	.744	141	9	1.000	127	21	.267	56	6	.052
	Composite	35	0	—	48	2		45	1		42	7		16	2	
	Other	3	0	—	5	0		5	0		4	1		1	1	

Ca(OH)₂, calcium hydroxide.

TABLE 3 - Association between the Quality of the Coronal Restoration and Pulp Capping Outcome

Follow-up	N (%)	Adequate		Inadequate		New caries		Success %	P value
		Success	Failure	Success	Failure	Success	Failure		
1 y	119 (52.9%)	119 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	100	—
5 y	212 (94.2%)	201 (96.2%)	8 (3.8%)	1 (50%)	1 (50%)	0 (0%)	1 (100%)	95	.007
10 y	191 (84.9%)	178 (96.7%)	6 (3.3%)	3 (42.9%)	4 (57.1%)	0 (0%)	0 (0%)	95	<.001
20 y	202 (89.8%)	160 (91.4%)	15 (8.6%)	13 (59.1%)	9 (40.9%)	0 (0%)	5 (100%)	86	<.001
35 y	82 (36.4%)	66 (94.3%)	4 (5.7%)	7 (77.8%)	2 (22.2%)	0 (0%)	3 (100%)	89	<.001

specialists in endodontics, using the operating microscope and adopting proper asepsis, while in many previous studies, treatments were rendered by undergraduate students or general clinicians. In a study where a setting calcium hydroxide paste was used as the pulp capping material, Barthel et al⁵ reported a success rate of 37% after 5 years and 13% after 10 years. Treatments were conducted by undergraduate students under the supervision of a faculty. Some teeth were restored with temporary fillings. In another study³³, the treated teeth were isolated with a rubber dam or cotton rolls and treated by dental students supervised by clinical instructors.

The following factors have not been reported to influence the pulp capping outcome: patient's age and sex, tooth type, pulp exposure size, and type and quality of restoration⁴. This was confirmed in the present study for most of these variables, but some were demonstrated to influence the treatment outcome. The inadequate quality of the permanent coronal restoration or the presence of new caries was the most relevant factor negatively affecting the long-term outcome. These conditions allow bacteria to reach and colonize the previously exposed area, and cause pulp inflammation as a consequence of diffusion of bacterial virulence

factors through dentinal tubules and/or the highly permeable irregular newly formed dentinal barrier^{34,35}. The initial analysis of independent variables showed that some other factors may also negatively affect the long-term outcome, including the pulp exposure size and number, which may predict the extent of pulp damage. The types of capping material and permanent restoration showed significant differences at the 35-year evaluation, but the sample size was substantially plagued by a very few samples in some groups. The multiple regression analysis confirmed the influence of the exposure size on the outcome at 5 years, with poorer results for large exposures, and included a significantly higher proportion of failures when varnish was used as the base over the capping material. Curiously, teeth with medium pulp exposures showed a failure rate much higher than the groups with small and large ones at 20-year and 35-year follow-ups. The reason for these findings is unknown, probably multifactorial and difficult to speculate.

In all cases with long-term follow-ups, either categorized as success or failure, the endodontic space appeared narrowed to a varying degree in the radiographs (Fig. 1A–C, 3A–D), with formation of varying amounts of

pulp stones in the pulp chamber (Fig. 4A–G) and sometimes diffuse fine calcifications in the root canals (Fig. 4G). Evaluation of calcific changes in the pulp tissue following pulp capping was not among the objectives of the present study. Such evaluation is, however, difficult to accomplish, given that narrowing of the endodontic space and formation of pulp stones are also observed in caries-free teeth after long observation periods. However, the so-called full pulp obliteration was not observed in any of the cases under investigation.

In conclusion, a very high success rate of the direct pulp capping of teeth with reversible pulpitis and using calcium hydroxide was observed, especially in the first 10 years following treatment. The main variable influencing the results was the quality of the coronal restoration. Case selection and careful clinical procedures are expected to make direct pulp capping a predictable therapy to save caries-exposed dental pulps.

CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

Domenico Ricucci: Conceptualization, Methodology, Investigation, Writing – original

TABLE 4 - Logistic Regression Analysis of Factors Affecting the Outcome of Pulp Capping

Independent variables	Effects of variables included in the regression equation				
	B	Standard error	Wald	Degrees of freedom	P value
Outcome - y 5					
Small exposure			4.517	2	.105
Medium exposure	2.262	1.744	1.682	1	.195
Large exposure	5.632	2.677	4.427	1	.035
Other bases: glass ionomer			4.995	2	.082
Other bases: varnish	−5.355	2.580	4.307	1	.038
Other bases: zinc oxiphosphate	−4.154	2.086	3.965	1	.046
Outcome - y 20					
Small exposure			9.853	2	.007
Medium exposure	−0.169	0.898	0.035	1	.851
Large exposure	−1.751	0.856	4.186	1	.041
Outcome - y 35					
Small exposure			2.691	2	.260
Medium exposure	13.258	6271.264	0.000	1	.998
Large exposure	−5.528	3.370	2.691	1	.101

draft. **Isabela N. Rôças:** Formal analysis, Data curation, Writing – review & editing. **Flávio R.F. Alves:** Software, Validation, Formal analysis. **Pedro H. Cabello:** Software,

Validation, Formal analysis. **José F. Siqueira:** Methodology, Validation, Supervision, Data curation, Writing – original draft, Writing – review & editing.

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